Summary of the
NELAC Quality Systems Committee Meeting
July 30, 1997

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) convened in Dallas on Tuesday, July 30, 1997, 12:30 - 5:00. The meeting was led by its chair, Ms. Sylvia S. Labie, of the Florida Department of Environmental Protection. A list of action items is provided in Attachment A and a list of committee members is given in Attachment B.

INTRODUCTION

The chair opened the meeting by introducing the outgoing committee members, Fred Siegelman and Rick Orthen, and the incoming members, Cliff Glowacki and Fred Haeberer.

The chair indicated that last year, approximately 90% of the standards the committee proposed were adopted. The chair then briefly summarized the revisions to the Quality Systems chapter under consideration at this meeting. The following points highlight these proposed revisions.

- Language was changed to reflect that all the requirements in this chapter are not mandatory for each specific project.
- Simplification of standards for subcontracting labs.
- Withdrawal of the radioanalysis section last year pending subcommittee review
- Rewording of the scope to limit additional requirements being imposed by States.
- Definition for small laboratories is 10 employees.
- Test Methods: addition of an appendix on Performance Based Measurement Systems.
- Reagents: separation of record keeping from that of standards
- Sample Disposal: need for SOPs for sample disposal and record retention
- Appendix B: amended definitions for batch, compromised sample, EDL, and tolerance chart.
- Appendix E: currently on hold.

The goals for the meeting were to review all the proposed revisions and prepare the document so that the remaining sections can be passed.

The following issues were identified for future consideration:

- addressing the determination of MDLs,
- calibration requirements (especially were they are not specified by method),
- Performance Based Measurement Systems,
- air test methods, and
- and whether field methods will be covered in the Quality Systems chapter.

The chair concluded the introductory remarks by encouraging meeting participants to volunteer to work on the committee.

DISCUSSION ON SPECIFIC QUALITY SYSTEMS SECTIONS

The following summary is organized around the specific sections of the Quality Systems chapter for which revisions were proposed and highlights the main points of discussion pertaining to these sections.

Performance Audits 5.5.3.4

A written comment from DOD suggested adding blind and double blind samples to the list of examples of performance audits checks. The committee responded that this section is not meant to be inclusive, just to provide examples.

A question was raised regarding the definition of a "periodic audit". The committee decided to address this at the Interim Meeting.

Laboratory Reports 5.13

Editorial changes were made to sections 5.13.g and 5.13.a.11. Refer to the Quality Systems document for these changes.

Questions were raised regarding standards and available guidance for the use of electronic signatures. The committee decided to keep the statement on electronic signatures. Available guidance can be referenced or more clearly defined in a later version of the chapter.

Subcontracting Analytical Services 5.14

A comment was made that the requirement for a laboratory to maintain a register detailing the scope of accreditation for any subcontracted laboratory could duplicate the NELAP register, and it could be difficult for a laboratory to keep current information on accreditation. In response to this comment, it was explained that the register can be an aid to auditors and the language complies with the ISO standards.

Radioanalysis D.4

A global question was raised regarding where a paragraph should be inserted to describe the relationship between QAPP requirements and those of the Standard (i.e., beginning of the document, beginning of Chapter 5, elsewhere)? The issue relates to serving the needs of the client, when they may be less stringent than required by the Standard. The committee decided the issue needs to be addressed outside today's forum.

Test Methods 5.10.2 and Appendix C

The language on Initial Demonstration of Capability (now in Appendix C) and Performance Based Measurement Systems were separated. 5.10.2 outlines where Initial Demonstration of Capability would apply and where Performance Based Measurement Systems would apply.

Editorial changes were made to Appendix C.1.a and e. Refer to the Quality Systems document for these changes.

It was noted that rather than require a certified source for the QC check material, the standard now calls for an outside source.

Introduction Section 5.0

Changes to this section were editorial and will not be voted on.

Scope Section 5.1

It was suggested that "mandated" be changed to "EPA required" in section 5.1.b. This comment involves two issues: (1) the desire to minimize States adding to the NELAP requirements and (2) recognizing that States may need additional methods for their environmental programs. The concern was that too many methods or requirements could defeat the purpose of NELAP and reciprocity. After discussion, the committee decided to leave "mandated" in the text.

Another suggestion was to change "regulation" to "EPA regulation" in section 5.1.b. The committee decided to leave the text as is.

The second paragraph of section 5.1.b was added to state that "additional requirements" refers to those requirements in the Quality Systems chapter and not other requirements that States may decide to add. The text of section 5.1.b was edited to state this intent more clearly utilizing an ISO/IEC Guide 25 statement.

A suggestion was made to delete section 5.1.c. It was explained that this section was adopted from ISO. This represents the minimum that a laboratory must do to become accredited and what an accrediting body would use to measure compliance with these requirements. Editorial changes were made to section 5.1.c.

References Section 5.2/Appendix A, Definitions Section 5.3/Appendix B, and Organizations and Management Section 5.4

The specific number of employees that defines a "small laboratory" in section 5.4.2.g was discussed. It was noted that the QA officer does not have to be a full-time job and multiple QA officers are allowed (i.e., technical staff from one section may perform QA on work in other sections.) A key issue is that a technician cannot perform QA on their own work. The text was edited to eliminate a numerical limit from 5.4.2.g to allow for more flexibility in the standard.

Quality System Section 5.5

A written comment from DOD suggested that 5.5.2.r be amended to address protecting national security issues. The committee decided to leave the text unchanged.

The text of 5.5.2.h was edited to reflect that Section 5.5.2.h does not preclude listing methods for which the laboratory is not accredited

It was stated that Section 5.5.2.i can possibly be interpreted in different ways. The meaning of this statement will be addressed at the Interim Meeting.

A comment was made regarding the use of the term "validity" in Section 5.5.4.b. The issue was that data may not meet quality control acceptance limits, but these data are not necessarily invalid or unusable. Such data may be useful with proper qualifications. Section 5.5.4.b was edited to reflect this comment.

Personnel Section 5.6

Changes made to this section were editorial and were not voted on.

Measurement Traceability and Calibration Section 5.9

Editorial changes were made to section 5.9.4.2.1.a. Refer to the Quality System document for these changes.

In section 5.9.4.3.a.2, the issue of allowing single point calibration was raised. It was decided to table this issue until a later time.

The quantitative criteria of this section were challenged from the perspective of Performance-Based Measurement Systems and Data Quality Objectives. This issue will be considered in future committee meetings.

In section 5.9.4.4.2.c, the issue of dealing with non-detects when a high bias has been encountered was discussed. Opinions differed and the question will need to be carefully considered.

Test Methods and SOPs Section 5.10

In section 5.10.5, the record keeping requirements for standards and reagents were separated.

Sampling Handling, Acceptance and Receipt Section 5.11

This issue of sample disposal was discussed. It was decided that SOPs should be developed for sample disposal and kept on file.

The term “compromised samples” was changed to “samples not meeting acceptance criteria” and the definition of compromised sample was deleted from Appendix B.

Records Section 5.12

There was no discussion on this section.

Chemical Testing Section D.1

Section D.1.4 was retitled Method Detection Limits.

This issue of the necessity to determine the MDL was discussed in detail and will be resolved at a later time.

Whole Effluent Toxicity Section D.2

Section D.2.1.a.3 was discussed; however, no changes were made to the text.

General Comments

The frequency of QC checks was discussed at length. Some of the comments on this issue were:

- a hierarchy of applicability could be used beginning with a specific project plan,
- this document should allow for more flexibility,
- a clear definition of project plan should be provided,
- section 5.5.2 .p might be able to be expanded as to how to deal with program requirements and QAPPs, and
- the more that is subject to laboratory and auditor judgement the more difficult accreditation may become.

It was decided that addressing these issues is beyond the scope of this meeting. The chapter will be voted on without any modifications, however, further consideration will be given to the comments at a later date.

A comment was made that it would be helpful if references include information on where to obtain the document.

In response to a question it was noted that guidance is not mandatory and standards are mandatory.

Internal Audits 5.5.3.1

The text in 5.5.3.1 was edited to address the issue of smaller labs not being able to afford an independent auditor. This issue also relates to the issue of the QA officer in 5.4.2.

Definitions Appendix B

Definitions of “legal chain of custody” vs “chain of custody” will be addressed at a later time.

Editorial changes were made to the definition of “confirmation”.

Attachment A

ACTION ITEMS
Quality Systems Committee Meeting
July 28, 1997

Item No.	Action	Date Completed
1.	Consider OSWER comments about prescriptive requirements and identify means of accommodating their needs.	First draft by interim meeting.
2.	Work on definitions of legal chain of custody, chain of custody, reporting limit, periodic audits, and bias.	3-4 months
3.	Refine/improve calibration requirements in 5.9.4.3 - 5.9.4.4.	For NELAC V
4.	Enhance/clarify certain topics such as electronic signatures.	3-4 months
5.	Consider the issue of method detection limits, when they are relevant, recommended alternatives to the current standard.	For NELAC V
6.	Performance Based Measurement Systems: incorporate final EPA version as Appendix E and propose for consideration as a standard.	For NELAC IV

Attachment B

LIST OF COMMITTEE MEMBERS
Quality Systems Committee Meeting
July 28, 1997

Name	Affiliation	Phone Numbers
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